UNITED STATES PATENT AND TRADEMARK OFFICE

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ART UNIT	PAPER NUMBER
2135	

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Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-90C (Rev. 10/03)

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>3</u> MONTH(S) FROM
THE MAILING DATE OF THIS COMMUNICATION.
- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed
  after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
  Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any
  earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on <u>22 December 2003</u>.

2a)☐ This action is **FINAL**.   2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is
closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) <u>1-20</u> is/are pending in the application.

    4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) <u>1-20</u> is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on <u>22 December 2003</u> is/are: a)☒ accepted or b)☐ objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

    a)☐ All   b)☐ Some * c)☐ None of:

      1.☐ Certified copies of the priority documents have been received.

      2.☐ Certified copies of the priority documents have been received in Application No. _____.

      3.☐ Copies of the certified copies of the priority documents have been received in this National Stage
application from the International Bureau (PCT Rule 17.2(a)).

    * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)

2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3)☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
    Paper No(s)/Mail Date _____.

4)☐ Interview Summary (PTO-413)
    Paper No(s)/Mail Date. _____ .

5)☐ Notice of Informal Patent Application (PTO-152)

6)☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1.   The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2.   Claims 1-7, and 11-18 are rejected under 35 U.S.C. 102(e) as being anticipated by McGauley (US 5,899,998).

      a.   *Referring to claim 1:*

          i.   McGauley teaches:

            (1)   selecting, by the individual, a record server that is publicly accessible over a network **[i.e., Figure 6, it is a new type of distributed database network system in which medical data items are automatically propagated from their sites of origin to several different memory storage sites, independently and selectively, such as, portable data carriers (PDC), medical point-of-service (POS) stations, and administrative services systems (column 2, line 30-37)]**;

            (2)   encrypting a confidential record of the individual **[i.e., are encrypted to help protect the security of the system and to preserve the confidentiality of individual patient's medical information (column 6, line 46-48)]**;

            (3)   storing the encrypted confidential record on the selected record server **[i.e., stored within their PDC, patients actually carry their medical data from one POS station to another (column 3, line 18-19)]**; and

            (4)   accessing the encrypted confidential record stored on the selected record server through a defined gateway system **[i.e., the PDCs also**

serve as one of the main communication links between POS stations, for example, when a patient visits their doctor, the patient's PDC is read/access by the doctor's POS station and this automatically transfer medical information between the PDC and the station, so that the more current data is propagated and stored in both places (column 3, line 17-19 and line 29-33)].

      b.   *Referring to claim 2:*

           i.   McGauley further teaches:

           (1)   the step of distributing an access token to a predetermined agent by the individual for use in accessing the stored confidential record over the network [i.e., **the PDC is a microprocessor integrated circuit chip card, commonly known as a smart card, which servers as a data storage device on which patients carry a copy of their own medical record. In addition, the carries physician orders, such as medication prescriptions, laboratory or X-ray tests, referrals to consultant physicians, surgical procedures and the like. When a patient visits their doctor, the patient's PDC is read/access by the doctor's POS station (column 2, line 41-56 and column 3, line 28-29]**.

      c.   *Referring to claim 3:*

           i.   McGauley further teaches:

           (1)   the predetermined agent is a healthcare institution [i.e., **the POS stations are computer systems positioned at locations where patients receive medical care, such as physician offices, pharmacies, laboratories, radiology units, hospitals, diagnostic and treatment centers, emergency treatment sites, and urgent care centers (column 2, line 59-64)]**.

      d.   *Referring to claim 4:*

           i.   McGauley further teaches:

           (1)   the confidential record is a medical record [i.e., **each PDC contains the medical record of an individual patient (column 1, line 15-16)]**.

      e.   *Referring to claim 5:*

           i.   McGauley further teaches:

     (1) the individual is a patient **[i.e., an individual patient (column 1, line 16)]**.

  f. *Referring to claim 6:*

    i. McGauley further teaches:

     (1) the predetermined agent is the patient who has privileges to read, modify, and annotate the medical record **[i.e., Figure 6, the patient manager 123 contains major rule sets relating to data processing, such as routing update objects and modifying databases (column 12, line 58-60)]**.

  g. *Referring to claim 7:*

    i. This claim has limitations that is similar to those of claim 6, thus it is rejected with the same rationale applied against claim 6 above.

  h. *Referring to claim 11:*

    i. McGauley further teaches:

     (1) the access token is a smart card **[i.e., the PDC is a microprocessor integrated circuit chip card, commonly known as a smart card (column 2, line 41-43)]**.

  i. *Referring to claim 12:*

    i. McGauley further teaches:

     (1) the step of accessing by the predetermined agent the encrypted confidential record on the record server from any node on the network capable of accepting the access token **[i.e., this independent PDC-POS database design allows "patient specific" and "site specific" medical data to be present when and where it is needed, at every medical POS location (column 3, line 10-13)]**.

  j. *Referring to claim 13:*

    i. McGauley further teaches:

     (1) the step of maintaining anonymity of the individual when the predetermined agent accesses the encrypted confidential record of the individual **[i.e., It may not be necessary for the pharmacy POS station to have access to all of the medical information on the PDC. Indeed, some of the**

information may be confidential or unnecessary to filling the prescription. The internally stored rule sets in the pharmacy POS station govern what information can be obtained from the PDC and what information is excluded (column 3, line 43-47)].

          k.   *Referring to claim 14:*

             i.   McGauley further teaches:

               (1)   the step of determining by the individual each portion of the confidential record that is accessible to the predetermined agent [i.e., **each patient's medical file is kept current at numerous independent databases by routing medical data through the system via update objects that interact with strategically placed rule sets. The general rules for processing update objects are located within each POS station, in the switching station, and in the administrative services system. The rules are shown in Figures 7 and 8 (column 15, line 23-32)**].

          l.   *Referring to claim 15:*

             i.   McGauley further teaches:

               (1)   the gateway system and the record server selected by the individual are the same node on the network [i.e., **Figure 6, a distributed database network architecture, in which a plurality of PDCs and POS stations interact to maintain the currency of the medical records of a plurality of patients. In addition to serving as one of the database repositories in this network, each PDC also serves as a communication link between the POS stations (column 1, line 12-15 and line 24-26)**].

          m.   *Referring to claim 16:*

             i.   McGauley further teaches:

               (1)   the step of defining a schema for representing the confidential record using a markup language [i.e., **Figure 6, the database conversion system 153 translates the information from the object-oriented structure to a relational database structure, which allows the invention to interact easily and**

efficiently via widely used standard protocols and query languages (column 14, line 62-64 and column 15, line 5-7)].

    n.   *Referring to claim 17:*

        i.   McGauley teaches:

        (1)   digital information representing a confidential record of the individual **[i.e., the computerized medical records where each PDC contains the medical record of an individual patient (column 1, line 10-15)]**;

        (2)   a publicly accessible server system connected to the network and selected by the individual for storing the confidential record **[i.e., Figure 6, the portable data carriers (PDC) (column 2, line 34)]**; and

        (3)   a gateway system, in communication with the server system, comprising software for accessing the confidential record of the individual **[i.e., Figure 6, the medical point-of-service (POS) stations are computer system positioned at locations where patients receive medical care (column 1, line 59-60)]**.

    o.   *Referring to claim 18:*

        i.   This claim has limitations that is similar to those of claim 2, thus it is rejected with the same rationale applied against claim 2 above.

Claim Rejections - 35 USC § 103

3.   The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4.   Claims 9,10, 19, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over McGauley, and further in view of Ho (US 6, 148, 342).

    a.   *Referring to claims 9, 10,19, and 20:*

        i.   McGauley teaches the claimed subject matter except for:

        (1)   the access token is a private cryptographic key.

(2)   the access token is a biometric of the predetermined individual that is measurable by a biometric hardware device.

ii.   However Ho teaches:

(1)   the use of public and private key cryptography, identifier is encrypted using a public key of an identifier database. The identifier package may also include the public key of the source terminal as shown in Figure 1. Furthermore, the entire data packet is signed in block 212 (as shown in Figure 2A where such encryption may be done with a private key of the source terminal **(column 5, line 59-64 and column 6 line 5-8).**

(2)   source terminal 104 (as shown in Figure 1) identifies or collects information to identify the user, typically by obtaining passwords, handprints, fingerprints, retinal scans, or other appropriate identification mechanism **(column 2, line 46-49).**

iii.   It would have been obvious to a person having ordinary skill in the art at the time the invention was made to:

(1)   include these kinds of identification information (such as Figure 6 of McGauley) for protecting confidential information as well as preventing insiders with high levels of computer access from accessing sensitive data **(column 1, line 11-13 of Ho).**

vi.   The ordinary skilled person would have been motivated to:

(1)   add these kinds of identification information (such as Figure 6 of McGauley) for protecting sensitive data because as data on the computer becomes increasingly sensitive and valuable, the system administrator or other "trusted insider" increasingly has incentives to defeat the protection mechanisms of the system and sell the confidential data **(column 1, line 33-37 of Ho).**

5.   Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over McGauley, and further in view of Melrose (US 6, 272, 468).

a.   *Referring to claim 8:*

i.   McGauley further teaches:

(1) the step of associating a class of agents with a set of privileges for accessing the confidential record, wherein the predetermined agent is a member of the class **[i.e., Figure 6, the POS database 122 is object-oriented. It is flexible in size. It stores and retrieves data according to key identifiers (column 12, line 48-50). The POS stations are computer systems positioned at locations where patients receive medical care, such as physician offices, pharmacies, laboratories, radiology units, hospitals, diagnostic and treatment centers, emergency treatment sites, and urgent care centers (column 2, line 59-64)].**

ii. However, McGauley does not explicitly mention the use of a class of agents or an agent is a member of the class, Melrose, on the other hand, teaches:

(1) Figure A2 shows the ChartSystem Package, medicalRecord Class **(column 5, lines 57-60).**

iii. It would have been obvious to a person having ordinary skill in the art at the time the invention was made to:

(1) have applied Melrose's teaching into McGGauley's system since a third category of medical computer systems is called the "electronic medical record" (EMR) or "computer-based patient record" (CPR)--the principal focus of attention during the past two decades, primarily through the efforts of the Computer-based Patient Record Institute (CPRI). Systems in this category address the issues of medical record content, utility and confidentiality in an effort to define, design and develop a computer-based "chart", the common practice name for the paper-based medical record as defined above **(column 2, lines 13-22 of Melrose).**

vi. The ordinary skilled person would have been motivated to:

(1) have applied Melrose's teaching into McGGauley's system because the principal purpose of the computer-based chart is to make patient-specific information available to clinicians when and where it is needed in order to facilitate more efficient, effective and (therefore) economical pathology diagnosis and treatment, and ongoing patient care including clinical monitoring **(column 2, lines 22-27 of Melrose).**

Conclusion

6.   The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

a.   Ballantyne et al (US 5, 867, 821) discloses a method and apparatus for distribution and administration of medical services, entertainment services, electronic health records, and education information useful in hospitals, other types of health care facilities, and patient's homes (column 1, line 12-16).

b.   Conner et al (US 5, 579, 393) discloses a system for secure medical and dental record interchange comprises a provider system and a payer system.   The provider system includes a digital imager, a processing unit, a data transmission/reception device, and a memory having a provider management unit and a security unit (see abstract).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thanhnga (Tanya) Truong whose telephone number is 571-272-3858.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kim Vu can be reached at 571-272-3859.   The fax and phone numbers for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-2100.

KIM VU
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 2100

TBT
March 21, 2005